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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,193	11/29/2000	Chih-Ming Chen	300.1023	6199
23280	7590	01/02/2004	EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/726,193

Applicant(s)

CHENG ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-20 and 24-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-20 and 24-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Examiner acknowledges receipt of amendment, request for extension of time and declaration filed 10/06/03.

#### ***Declaration***

The declaration filed on 10/06/03 under 37 CFR 1/131 eliminates the Timmins reference (US 6,475,521) as prior art since applicants declare that the invention under examination occurred at a date earlier than the earliest effective date for the Timmins reference.

#### ***Claim Rejections - 35 USC § 112***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claims 1-4 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to claim 1.
3. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 36 recites the limitation "the evening meal" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 35 does not recite evening meal.

#### ***Claim Objections***

5. Claims 2, 7 and 34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to

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cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 1, 6 and 32 upon which claims 2, 7 and 34 respectively depend from are composition claims.

In claim 1, a recitation of providing a "therapeutic plasma level ... to said patient" is a property of the formulation and the "administration" recited in said claim 1 is an intended use or application of the formulation. Claim 2, which limits claim 1 to administration does not further limit claim 1 since claim 1 is directed to a composition and not to method of administration.

Claim 6 is directed to a composition and the "administration" in the claim is an intended use of the formulation. Thus claim 7 does not further limit claim 6.

Claims 31 and 32 are composition claims and the recitation of "orally administered" in claim 31 is the route of administration of the formulation and thus carries no patentable weight in said claims. Thus, claim 34 does not further limit claim 32 by limiting claim 32 to administration.

Applicants' arguments with respect to the art rejection on record regarding the pending claims have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1-4, 6-20, 24-32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott (US 3,621,097).

Scott discloses a sustained release formulation (column 4, lines 32-35) that comprises dimethyl biguanide, which is metformin (STN registry file); and Scott in example 4 discloses preparation of coated tablet that contains granules of dimethyl biguanide.

The instant claims are directed to sustained release formulation of metformin. The instant claims fail to recite specific doses or amounts of metformin. The instant claims recite the property and intended use of the formulation, and a future intended use of a composition is not critical in a composition claim since no patentable weight is accorded to the composition by the intended use. A recitation of the property of the formulation does not accord patentable weight to a sustained release formulation of metformin over the sustained release formulation of the prior art. A property of a composition is inherent to that composition and said property cannot be separated from the formulation.

It is respectfully noted that the instant claims do not recite any specific dose that would exclude the metformin of dimethyl biguanide formulation of Scott from having the property of providing a therapeutic plasma level in a 24-hour period when Scott's formulation is administered to a subject or to treat mental illness.

The influence of food on the bioavailability of metformin is a property of metformin. Regarding the dissolution profile of the instant metformin formulation, the metformin formulation of Scott would also have the claimed dissolution profile; since no amount or dose of metformin is claimed or recited in the instant claims, the dissolution profile recited in the instant claims appears not to be unique to the formulation of the instant claims, rather any sustained

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release metformin formulation of the form recited in the instant claims would inherently exhibit said dissolution profile.

Scott discloses the sustained release formulation of the instant claims and thus meets the limitations of the claims.

In the remarks filed on 10/06/03, applicants state that the formulation of Scott is used to treat mental illness. This argument is not persuasive because treating mental illness is a future intended use and a future intended use is not critical in a composition claim. Furthermore, applicants state that the disclosure of Scott is not enabling for the preparation of sustained release metformin. However, this argument is not persuasive because it is within the purview of the person of ordinary skill or one skilled in the art to be able to prepare sustained release formulation; secondly, Scott in example 4 prepares coated tablets containing granules of metformin and thus provides the necessary direction to prepare the sustained release metformin formulation.

8. Claims 1-4, 6-20, 24-32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (US 5,055,306).

Barry discloses sustained release formulation of a pharmacologically active substance (abstract) and metformin, drug that acts on endocrine system or drug used in diabetes (column 7, lines 3-10, 35 and 36). Barry further discloses administering the formulation to a human subject (column 11, lines 39). The instant claims recite the property and intended use of the formulation, and a future intended use of a composition is not critical in a composition claim since no patentable weight is accorded to the composition by the intended use. A recitation of the property of the formulation does not accord patentable weight to a sustained release

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formulation of metformin over the sustained release formulation of the prior art. A property of a composition is inherent to that composition and said property cannot be separated from the formulation.

It is respectfully noted that the instant claims do not recite any specific dose that would exclude the metformin formulation of Barry from having the property of providing a therapeutic plasma level in a 24-hour period when Barry's formulation is administered to a subject.

The influence of food on the bioavailability of metformin is a property of metformin. Regarding the dissolution profile of the instant metformin formulation, the metformin formulation of Barry would also have the claimed dissolution profile; since no amount or dose of metformin is claimed or recited in the instant claims, the dissolution profile recited in the instant claims appears not to be unique to the formulation of the instant claims, rather any sustained release metformin formulation of the form recited in the instant claims would inherently exhibit said dissolution profile.

Barry discloses the metformin formulation of the instant claim and thus meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (US 5,055,306).

Barry discloses the instant sustained release metformin formulation. Barry discloses that metformin is used to treat diabetes (column 7, line 36) and also discloses administering the

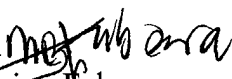
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formulation to a human (column 10, line 39). Regarding administering metformin formulation with or shortly after the evening meal, it is within the purview of the person of ordinary skill or the skilled artisan to ascertain the ideal times for administering the formulation. However, Barry fails to specifically disclose a method of treating diabetes. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the formulation of Barry to a subject in need thereof according to the disclosure of Barry. One having ordinary skill in the art would have been motivated to administer the formulation of Barry to a human diabetic subject with the expectation that the metformin will have the known effect of treating diabetes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

  
Blessing Fubara  
Patent Examiner  
Tech. Center 1600